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Topic: **510K Summery**
EMS-XL Cardiac Electrophysiology system

Establishment Name, Registration Number and Address:

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The following information is being submitted in conformance with [807.92(a)(2)].

1. Device Name:	EMS-XL - Cardiac Electrophysiology System
2. Classification Name:	Programmable Diagnostic Computer
3. Trade/Proprietary Name:	EMS-XL Cardiac Electrophysiology System
4. Common/Usual Name	Cardiac Electrophysiology system
5. Classification Number:	870.1425 computer, diagnostic, programmable 870.1750 External programmable pacemaker pulse generator.
6. FDA Classification	Class II
7. Product Code	DQK

8. Predicated Devices:
   Substantial Equivalence is claimed to the following devices:
   - K993414 (4 July 2000) – Cardiolab EP system. Prucka Engineering, Inc
   - K011826 (24 Jan 2002) – Micropace model EPS 320. Micropace Pty Ltd.

Device description

The EMS-XL Cardiac Electrophysiology System consists of a software driven, multichannel amplifier and stimulator that are connected to a computer.
Input signals include 12 lead surfaces ECG, two Blood pressure channels and 18 or 50 channel intra-cardiac ECG.
The signals are digitized and sent to the computer for analysis, display and storage.
Signals are displayed with sweep speeds of 25 to 300mm/sec in either predefined or customized configurations.

The system consists of a computer, Front end amplifiers with integrated stimulator.
Two display screens, one used for Real Time signal display and the other for Non real Time display for analysis and review and playback of stored signals.
A Laser printer is used to print surface and intra-cardiac ECG and a CD or DVD is used for archive of signals.

The two display screens are used to show the signals. The real time display, RT, shows the real time signal waveforms. Each waveform channel is color-coded for easy identification.
The non real time display, NRT, serves as a Review monitor allowing the manipulation and processing of data, including caliper measurements, event marking, snapshot storage and final report processing.
The stimulator is computer controlled and provides basic stimulation rate plus up to 4 stimulations delayed after the basic stimuli. Stimulation can be either synchronized to the cardiac electrical activity or non synchronized. Pacing protocols with automatic increment and decrement functions provides refractory period measurements.
A variety of stimulation sequences can be created and stored for future use.
The EMS-XL can be used for all types of electrophysiological procedures, including His bundle recording, Sinus Node Recovery Time – SNRT, Overdrive, Wenckebach, and tachy-arrhythmias.
An interface to ablation generators provide Ablation Start and End information with data on the ablation parameters.
Each waveform is color-coded for easy identification.
The review monitor allows the manipulation and processing of data, including caliper measurements, event marking, snapshot storage and final report processing.
Special display options support the signal analysis
This includes Trigger mode and template comparison, Event marking, Holter mode: quick, minute-by-minute scrolls and jumps to event, On screen calipers: both real-time and review screen with auto measurement , Auto Tachycardia detection, Free text labeling, and Customized reports in Word™.
The input to the amplifiers is via a patient connection box, to which the intra-cardiac catheter electrodes (not manufactured and not supplied by Mennen Medical) are connected.

Indication for use:

EMS-XL is indicated to acquire, filter, digitize, amplify, display and record electrical signals obtained during electrophysiological studies and related procedures conducted in an electrophysiological laboratory. Signal types acquired include ECG signals, direct cardiac signals and pressure recordings. Physiological parameters such as the diastolic, systolic and mean blood pressure, heart rate and cycle length are derived from the signal data, displayed and recorded.

The system allows the user to monitor, display and record the signal data.

The system allows the user to monitor the acquisition data, review the data, store the data, perform elementary caliper-type measurements of the data, and generate reports on the data. The system may display and record data received from other medical devices typically used during these procedures, such as Ablation RF generators. The system incorporates a stimulator intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the human heart.

The intended use

The EMS-XL is a computerized Electrophysiological Measurement System, designed for conducting regular or experimental electrophysiology (EP) studies.
The EMS-XL System is intended to be used for performing computerized Electrophysiological and Ablation procedures.
The EMS-XL is intended for sale as a system for performing EP clinical studies
Prescription Use under the supervision of a physician

Control and Integration

The EMS-XL integrated stimulator allows complete control of all stimulator functions at all times, featuring programmable pacing protocols with automatic increment and decrement functions, comprising all basic modes. Furthermore, the system includes online Holter and Event windows that allow for simple and immediate tracking of ectopic events. Fully editable final reports are generated in a Microsoft Word™ format, easily integrating measured intervals and procedure notes, to improve efficiency and productivity while saving valuable staff time.

Additional Features

- Trigger mode and template comparison
- Customized reports in MS Word™
- Auto Tachycardia detection: Jump to event
- SNRT Protocol
- Automatic snapshot after pacing
- Event marking
- Holter mode: Quick, minute-by-minute scrolls and jumps to event
- On screen calipers: Both real-time and review screens with auto measurement

- Export snapshots as image file for a PowerPoint presentation
- Multiple interfaces to Ablation RF generators for display of ablation parameters and ablation stop/start events
- Total case full disclosure archiving on hard drive
- Easily upgradeable software

Product Highlights

- Built-in integrated stimulator:
- Total full disclosure: Guaranties data integrity and long term archiving
- Off-line review station: Review, analysis and printing of entire case from remote location (optional)

Product Comparison to predicated devices

The EMX-XL system combined signal amplification, display and recording features with stimulation capabilities.
We thus have two predicated devices:

- Cardiolab EP system. Prucka Engineering, Inc – K993414 (4 July 2000) for the signal amplification, display and recording
- Micropace model EPS 320. Micropace Pty Ltd. – K011826 (24 Jan 2002) for the stimulation specification and features.

The following are the comparison tables:

- Amplifier Spec comparison
- Comparison of Systems
- Stimulator Spec Comparison

Amplifier Technical Specifications comparison

Manufacturer	Predicated – GE Pruka	Mennen Medical	Effect on safety	Effect on Intended use
System	**CardioLab II Plus Amplifier**	**EMS-XL amplifier**		
Item	**Description**	**Description**		
Physical Specifications				
64/32 channel HxWxD	9.5x 14.0x 14.0 in	32 = 4.5x 11.5x 8 in x 64 = 9.0x 11.5x 8 in x	No	No
128/96 channel HxWxD	14.0 x 14.0 x 14.0 in	Not used	N/A	N/A Note 1
Environmental Specifications				
Temperature Operating	0°C to +35°C	Same		
Transport/Storage:	-15°C to + 50°C	-30°C to + 65°C	No	No
Humidity Operating:	< 95% relative at 35°C non-condensing	30% - 75% non condensing	No	No
Humidity Transport/Storage:	< 95% relative at 35°C non-condensing	5% - 95% non condensing	No	No
Power Specifications:				
Power Requirements	100-240 V AC; 50-60 Hz	Same		Same
Power Input (64/32 channel)	0.0-0.5 Amps Class I, Type CF Continuous operation	+ 5 V , 0.0 – 0.2 A + 12 V, 0.0 – 0.3 A – 12 V , 0.0 – 0.3 A	No	No
Power Input (128/96 channel)	0.5-0.75 Amps Class I, Type CF Continuous operation	Not used	N/A	N/A Note 1
Design				
Sampling and Hold	Each channel sampled prior to acquisition.	Same		Same
Sampling Rate	1K, 2K and 4K	1KHz	No	No Note 2
CMMR	100 dB min	Same		Same
Input Impedance	> 1 Billion Ohms	Typical 20 MΩ Above the 2.5 MOhm required by the ANSI/AAMI EC11 par 3.2.9	No	No Per standard
Leakage Current				
Patient Source:	< 10 uA	Same – Per ISO 60601-		Same

...anufacturer	Predicated – GE Pruka	Mennen Medical	Effect on safety	Effect on Intended use
System	**CardioLab II Plus Amplifier**	**EMS-XL amplifier**		
Item	**Description**	**Description**		
		1		
Patient Sink:	< 10 uA	Same – Per ISO 60601-1		Same
Patient Sink (measured at patient leads under single fault conditions):	< 50 uA	Same – Per ISO 60601-1		Same
Chassis Leakage:	< 100 uA	Same – Per ISO 60601-1		Same
ECG Input				
Outputs	12 lead ECG produced	Same		Same
High Pass Filter	0.05 Hz, 0.5 Hz, 5 Hz	0.05, 0.2, 40, 80 Hz	No	No Note 3
Low Pass Filter	100 Hz	Same		Same
RF Filtering	All inputs	Same		Same
ain	50-10,000 in 8 settings	Between 0 and 255 mm/mVolt – Continuous	No	Note 4
Saturation Recovery	Less than 1 sec.	Same		Same
Notch Filter	Power line (50/60 Hz)	Same		Same
Dynamic range	No data	+/- 5 mVolt AAMI EC11 par 3.2.3		Per standard
Baseline correction	No data	+/- 300 mVolt AAMI EC11 par 3.2.3		Per standard
Input / Output				
Inputs 32 channels	32 intracardiac inputs, 4 pressure inputs, 10 ECG inputs	36 intracardiac inputs (18 channels), 2 pressure inputs, 10 ECG inputs (12 channels)	No	No Note 5
Inputs 64 channels	96 intracardiac inputs, 4 pressure inputs, 10 ECG inputs	100 intracardiac inputs, (50 channels), 2 pressure inputs, 10 ECG inputs (12 channels)	No	No Note 5
Inputs 96 channels	160 intracardiac inputs, 4 pressure inputs 10 ECG inputs	Not used	No	No Note 1
Inputs 128 channels	224 intracardiac inputs, 4	Not used	No	No

...anufacturer	Predicated – GE Pruka	Mennen Medical	Effect on safety	Effect on Intended use
System	**CardioLab II Plus Amplifier**	**EMS-XL amplifier**		
Item	**Description**	**Description**		
	pressure inputs, 10 ECG inputs			Note 1
Outputs	16 channels/Block. Up to 112 channels. 32 channel: Block A 64 channel: Blocks A-C 96 channel: Blocks A-E 128 channel: Blocks A-G	No outputs	No	No Note 1
Switching	Any input can be switched to any output within a Block.	Each channel can be either Bipolar or Unipolar with Manual switching	No	No Note 6
High Pass Filter	DC, 0.05 Hz, 0.5 Hz, 5.0 Hz, 30 Hz, 100 Hz	0.05, 0.2, 40, 80 Hz	No	No Note 7
Low Pass Filter	500 Hz, 2,000 Hz	500 Hz	No	No Note 8
RF Filtering	All inputs	Same		Same
Gain	50-10,000 in 8 settings	Between 0 and 255 mm/mVolt – Continuous	No	No Note 4
Saturation Recovery	Less than 1 sec.	Same		Same
Notch Filter	Power line (50/60 Hz)	Same		Same
Dynamic range	No data	+/- 5 mVolt AAMI EC11 par 3.2.3		Per standard
Baseline correction	No data	+/- 300 mVolt AAMI EC11 par 3.2.3		Per standard
Pressure Inputs				
Inputs	Compatible with all standard external pressure transducers. 5uV/V/mmHg	Same		Same
Input Impedance	> 1 Billion Ohms	Typical 20 MΩ Above the 2.5 MOhm required by the ANSI/AAMI EC11 par 3.2.9	No	No Per standard
Outputs	Up to 4 pressure channels	2 pressure channels	No	No Note 4
Low Pass Filter	6 Hz, 25 Hz, 100 Hz, 400 Hz	DC to 12 Hz (DC to 40 Hz optional). IEC 60601-2-34 Standard par. 51.103 requests at least DC to 10 Hz.	No	No Per standard
Excitation Voltage	5V DC	10 V DC (+5 to -5V).	No	Note 9

...anufacturer	Predicated – GE Pruka	Mennen Medical	Effect on safety	Effect on Intended use
System	CardioLab II Plus Amplifier	EMS-XL amplifier		
Item	Description	Description		
Output Impedance	< 0.050 Ohms	Same		Same
Range	-400mm Hg to +400 mmHg	Same		Same

Stimulator Specification comparison

Manufacturer	Micropace Pty. Ltd. Austria Predicated device	Mennen Medical Ltd. Israel	Effect on safety	Effect on Performance
Subject/Parameter	**EPS320**	**(integrated in) EMS-XL**		
)A Concurrence	Yes K011826	Pending		
Isolated Stimulus channels	2	2		
Pulse Amplitude				
Range	0.1 to 25 mA into 800 Ω load	0.1 to 25 mA into 1500 Ω load	No	Note 10
Increment	0.1 mA up to 1 mA Amplitude	0.1 mA within whole range	No	No
Accuracy	+/- 2% or +/- 0.2 mA (whichever is larger)	Same		Same
Pulse duration				
Range	0.5 to 10 msec	0.1 to 9.9 msec	No	No
Increment	0.5 – 10 msec, increment of 1-10 msec	0.1 msec	No	No, smaller increments
Accuracy	+/- 0.15 msec	Same		same
Inter-stimulus Interval (ISI)				
Range	180 msec to 9990 msec +/- 1msec or 0.1% (whichever is greater)	Same		Same

Manufacturer	Micropace Pty. Ltd. Austria Predicated device	Mennen Medical Ltd. Israel	Effect on safety	Effect on Performance
Subject/Parameter	**EPS320**	**(integrated in) EMS-XL**		
Range (Burst)	30 – 9900 msec +/- 1msec or 0.1% (whichever is greater)	Same		Same
Increment	1 msec	10 msec	No	Note 11
Sequential Delay (AV)				
Range	10-1000+/- 1 msec (maximum ISI – 50 msec)	11 – 250 msec	No	Note 12
Increment	1 msec	same		
Programmed Protocols	Threshold SNRT Burst Overdrive Multi- Sx	Threshold panel key SNRT panel key Vent. Burst key Atrial Burst key Vent. Overdrive key Atrial Overdrive key Same	No	No
Programmed Protocols	Pace Wenkebach Nodal ERP / RSync_S2	Same User defined protocol User defined protocol	No	No
Programmable Protocol Key	5	Same		
Number of Extra-stimuli	6(S2-S7)	4(S2-S5)	No	Note 13
Sensing (ECG synchronization)				
Automatic or Manual trigger setting – sensitivity	External: 50 – 2000 mV Internal: Pacing catheter tip	Internal from any surface or intra-cardiac channel	No	No
Automatic or Manual trigger setting – Trigger lockup (refractory time)	5 - 5000 msec	Same		Same
Automatic or Manual trigger setting – ECG delay	5 - 5000 msec	Same		Same

Manufacturer	Micropace Pty. Ltd. Austria Predicated device	Mennen Medical Ltd. Israel	Effect on safety	Effect on Performance
Subject/Parameter	**EPS320**	**(integrated in) EMS-XL**		
Additional Outputs	Stimulus channel A:Sync 3 Input marker Stimulus channel **A**:Sync 3 Input marker Programmable Auxiliary / Paper advance: Sync 1 Input marker ECG trigger marker: Sync 1, Sync 2 .	No	No	Note 14
Power Source	Mains 220/110 to 14.5 VDC, 750 mA low voltage power supply. Backup Power: battery	Integrated with Amplifier + 5 V , 0.0 – 0.2 A + 12 V, 0.0 – 0.3 A – 12 V , 0.0 – 0.3 A	Yes	Note 15
Stimulation module		N/A		
Dimension	3.0x12.9x14.0 inch	N/A		
Weight	18.7 lbs.	N/A		
Control terminal				
Isolation Transformer		Yes		Note 15
Environment		Stimulator integrated with amplifier		
Operating Temperature	+10 to +40 Celsius	0°C to +35°C	No	No, Note 15
Storage Temperature	-20 to +60 Celsius	-30°C to + 65°C	No	No, Note 15
Operating Relative humidity	20% to 90% non-condensing	30% - 75% non condensing	No	No, Note 15
Storage Relative humidity	20% to 90% non-condensing	5% - 95% non condensing	No	No, Note 15
Operating altitude	0 to 4572 meter	- 400 to 3050 meter	No	No
Storage Altitude	0 to 7620 meter	- 400 to 5000 meter	No	No
Controller	Embedded micro-controller	Integrated into the Amplifier and computer	No	No, Note 15

Manufacturer	**Micropace Pty. Ltd. Austria** **Predicated device**	**Mennen Medical Ltd. Israel**	**Effect on safety**	**Effect on Performance**
Subject/Parameter	**EPS320**	**(integrated in) EMS-XL**		
		control		
User Interface	PC windows-style graphical display	Same on the EMS-XL display	No	Note 15
Power supply	Class II	See EMS-XL computer	No	Note 15
Isolation transformer	Toroidal 1 :1 medical grade, 110-240 VAC, 100 VA max	See EMS-XL computer	No	Note 15
0/S Software:	Custom RTOS / Datalight ROM-DOS	See EMS-XL computer	No	Note 15
Backup power	12V 2.1 Ah sealed lead acid	See Note A.	No	Note A
Emergency power:	9V LiMn02i PP3, 10y life	See Note A.	No	Note A
Operating time	Two (2) hours on backup battery	See Note A.	No	Note A
Pacing Channels				
Isolated Channels(3)	(i) Atrial and (ii) Ventricular via green Redel 4 pin socket (iii) Emergency Fixed Pace Output to Ventricle, via red Redel 4 pin socket	Same function with different connectors	No	Same
Power Source:	Internal DC-DC converters	See Note A.	No	No, Note A
Circuit Isolation:	Compliant with IEC601-1, Class CF, 5kV, common & differential mode	Compliant with IEC60601-1, Class CF, 5kV, common & differential mode	No	No
Computer Controlled Stimulus Pulses				
Current:	0.1 to 25 mA into 800 Ω load	0.1 – 25.5 mA, into 1500 Ω load 40V	No	Note 10
Current Steps:	0.1 mA	0.1 mA		Same

Manufacturer	Micropace Pty. Ltd. Austria Predicated device	Mennen Medical Ltd. Israel	Effect on safety	Effect on Performance
Subject/Parameter	**EPS320**	**(integrated in) EMS-XL**		
Accuracy:	+/- 2% or +/- 0.2 mA, which ever is greater	+/- 0.1 mA		
Pulse Duration:	0.5 ms, 1-10 ms in steps of 0.1ms	Pulse width 0.1 – 9.9 mSec steps of 0.1 mS	No	No
Accuracy:	+/- 0.15 ms	+/- 0.1 mA		Same
Load Impedance:	200-1000 Ω, <700 Ω for max current	1500 Ω	No	Note 10
Max Output Voltage	27V	40 V	No	Note 10
Inter-stimulus Intervals				
S1 Range:	180 - 9990 ms (Pace) 30 - 9990 ms (Burst Pace)	Same		Same
Stability:	Quartz computer clock, +/- 30 parts per million @ 25° C	Same		
Extra-Stimuli:	6 max, S2-S7, independent	4 max, S2-S5, independent	No	Note 13
Coupling interval:	30 - 9990 ms	Same		Same
Accuracy	+/- 1 ms or 0.1 % whichever is greater	+/- 10 ms	No	Note 11
Protocol Automation				
Auto decrement / increment:	Yes	Same		Same
	SNRT S1 intervals and RT calculation	Same		Same
	Auto pace and sense -	Same		Same
	His-coincident extra-stimulus timing calculation	Caliper with labels	No	Same function
	ATP S1 calculation from % of TCL	No	Yes	Note 16
	Trigger output on sensed ectopic beats	No	Yes	Note 16

Manufacturer	Micropace Pty. Ltd. Austria Predicated device	Mennen Medical Ltd. Israel	Effect on safety	Effect on Performance
Subject/Parameter	**EPS320**	**(integrated in) EMS-XL**		
	Stop On Tachycardia	No	Yes	Note 16
	All automation subject to instant operator adjustment	Same	No	Same
Backup Manually Controlled Stimulation		No backup stimulator Use external backup stimulator	Yes	Note 17
Emergency Backup Pacing		No backup stimulator. Use external backup stimulator	Yes	Note 17

Comparison of Systems

anufacturer	GE – Prucka Predicated device	Mennen Medical Ltd.	Effect on safety	Effect on performance
Subject/Parameter	**Carto® XP System Bi-directional Interface**	**EMS-XL**		
Processor/Data Storage				
Processor	Intel® 2.66GHz Pentium IV Xeon or greater	• Intel® 2.4GHz Pentium IV or greater	No	No
RAM	512 MB	Same		Same
Hard drives	2 x 40 GB	80 GB	No	No
Diskette Drive	No	1.44 MB	No	No
DVD-RAM/CD-RV drive	• 9.4 GB DVD-RAM/CD-RV drive	DVD-RW / CD R	No	No
Magnetic Optical Drive	• 2.6 GB Magnetic Optical Drive	Optional	No	No
Mouse	• Optical Scroll Mouse	same		Same
Operating System	• OS: Windows XP	Same		Same

Manufacturer	GE – Prucka Predicated device	Mennen Medical Ltd.	Effect on safety	Effect on performance
Subject/Parameter	**Carto® XP System Bi-directional Interface**	**EMS-XL**		
	Professional			
Office	• Microsoft Office XP Professional	Same		Same
Modem				
Modem	• 56K B. 90 Baud Data	Same		Same
Networking				
Ethernet	• 100 Base-T Ethernet, TCP/IP	Same		Same
Flat panel display	• 20" flat panel ultra high-resolution color	Same		Same
Monitors				
solution	• 1600 x 1200	Same		Same
No of monitors	1 or 2	2	No	No
Printer Options				
Black/White	• HP Black/White LaserJet 2300	HP LaserJet 4100 or greater	No	No
• Color LaserJet	Yes	No	No	No
Compliance with Standards				
standards	• UL 2601-1, IEC 60601-1-2, European Union Medical	Same		Same
Device Directive (CE Marked)	Device Directive (CE Marked)	Same		Same
Environmental/Electrical Specifications				
• Operating Temperature:	+10°C to +30°C	0°C to 35°C	No	No
• Storage Temperature: -	-10°C to +45°C	-20°C to 65°C		
• Humidity: operating	30%-75% (non-condensing)	Same		Same
Humidity: storage	10%-95%, (non-condensing)	5%-95%, (non-condensing)	No	No

Manufacturer	GE – Prucka Predicated device	Mennen Medical Ltd.	Effect on safety	Effect on performance
Subject/Parameter	**Carto® XP System Bi-directional Interface**	**EMS-XL**		
• Maximum Current Draw:	15A/115V, 7A/230V	Same		Same
• Chassis Leakage Current:	<100μA	Same		Same
Advance Features				
IT Interface	Yes	Yes		Same
Holter	Yes	Integrated Holter mode with full disclosure,.	No	No
Ablation	Connectivity to RF Ablation generator(s)	Same		Same
Statistics and Inventory	Xi2 Data Management System.	No	No	Note 18
Documentation	Configurable electronic documentation	Configurable Word documentation	No	No - Same
Networking	Remote waveform review and Nurses' Workstation, for simultaneous data entry with waveform archive	Remote Review station	No	No - Same
Security	Standard security features	Same		
Access to raw data	Easy access to raw waveform data (data extraction), binary & ASCII formats	Yes , in Full Disclosure	No	No, Same

Manufacturer	GE – Prucka Predicated device	Mennen Medical Ltd.	Effect on safety	Effect on performance
Subject/Parameter	**Carto® XP System Bi-directional Interface**	**EMS-XL**		
Mapping	Isochronal and Isopotential Maps	No	No	Note 19
Vital Signs	Integrated Vitals Monitoring with Audible Indicators	Not integrated	No	Note 20

Certification		
MDD Device Class:	Class IIb	Class IIb
IEC60601-1	certified	certified
EMC compliance	certified	certified
CE Marking	certified	Certified CE 0473
US Regulations	510(k) Accepted	Applied

Note 1: The stimulator is integrated with the amplifier and controlled by the EMS-XL software – Thus it does not have a separated power supply and battery backup.

Dimensions						
System Dimension	**Width cm/ inch**	**Depth cm/ inch**	**Hight cm/ inch**	**Width cm/ inch**	**Depth cm/ inch**	**Hight cm/ inch**
	Workstation (65")			**Cart with display**		
	165/65	76/30	172/77	61/24	61/24	162/64
	Workstation (45")			**Consol with display**		
	114/47	76/30	75/30	90/35	85/33	125/50
	Workstation (Box)					
	61/24	71/28	75/30			
Amplifier Dimension	**32/64 Channel**			**32 Channel**		
	36/14	36/14	24/10	29/11	22/9	11/5
				64 channel		
				29/11	22/9	22/9

	Predicated – GE Pruka	**Mennen Medical – EMS-XL**
Certification		
MDD Device Class:	Class IIb	Class IIb
IEC60601-1	certified	certified
EMC compliance	certified	certified
CE Marking	certified	Certified CE 0473
US Regulations	510(k) Accepted	Applied

Note A : The stimulator is integrated with the amplifier and controlled by the EMS-XL software – Thus it does not have a separated power supply and battery backup.

Rational for claims of equivalence of Mennen Medical EMS-XL amplifier and GE Prucka Plus Amplifier

Subject	Reduced safety	Is EMS-XL as safe and effective as the Plus Amplifier (Rational)
Note 1- No. of channels	No	Assumed equivalence to the 32/64 channel Plus Amplifier and not to the 128 channel amplifier
Note 2- Sampling rate	No	Assumed equivalence to the 1 KHz sampling rate. This sampling rate meets the requirements for clinical practice and sufficiently shows conduction pathway potentials clearly.
Note 3 – ECG High Pass filter	No	Both systems provide 0.05 Hz diagnostic filter that show high fidelity ECG. 0.5 Hz (Plus Amplifier) and 0.2 Hz (EMS-XL) provides a faster response to electrode movement, with same QRS detection capability. The EMS-XL 40 and 80 Hz filters yields the best deflection of HRA, HIS bundle and ventricle electrocardiogram.
Note 4 – ECG gain	No	The gain of the two systems is equivalent and only uses different terms. The term mm/mVolt used by EMS-XL shows the relation between the signal amplitude in mVolt and the display amplitude in mm. EMS-XL has continuous gain control that covers the whole gain range instead of the 8 steps of the Plus Amplifier
Note 5 - Number of channels	No	Assumed equivalence to the 32/64 channel Plus Amplifier and to 2 of the 4 pressure channels. 32/64 channel system is clamed to cover a wide range of clinical application.
Note 6 - Channel switching	No	The difference in this switching capability is practically overcome by manual switching of electrodes between inputs that using the Bipolar input
Note 7 – IECG high pass filter	No	The set of filters provided by EMS-XL provide the necessary filtration for detection of fast changing intra-cardiac signals and cover the same range of filters of the Plus Amplifier and the changes between 30 and 40, and between 80 and 100 are not significant.
Note 8 IECG low pass filter	No	EMS-XL has same 500 Hz filter as the Plus Amplifier. As stated in Note 2, Mennen claims equivalence to the 1 KHz sampling rate. This sampling rate meets the requirements for clinical practice and shows intra-cardiac potential clearly. The low pass filter of 2000Hz is not relevant for sampling rate of 1 KHz
Note 9 Excitation voltage	No	The important parameter for transducers is the sensitivity, that is 5μV/V/mmHg (industry standard), and this is same for both amplifiers

Rational for claims of equivalence of Mennen Medical EMS-XL stimulator and Micropace Pty EPS320

Subject	Reduced safety	Is EMS-XL as safe and effective as the EPS320 (Rational)
Note 10 Stimulation current	No	The EMS-XL stimulator and the predicated EPS320 stimulator are both constant current stimulators and cover the same current range with the EMS-XL source is up to 1500 Ω, and EPS320 only 800 Ω This effects the maximal stimulation voltage.
Note 11- Stimulation increment	No	The EMS-XL stimulator has increments of 10 mSec that provide easier control than 1 mSec increment of the EPS320.
Note 12- AV delay	No	EPS320 =10-1000+/- 1 msec (maximum ISI – 50 msec) EMS-XL =11 – 250 msec - No clinical significance in usin longer intervals
Note 13 No. of stimuli	No	EMS-XL has S1 and 4 extra stimuli, EPS320 has 6 extra. In almost all clinical applications 4 extra are sufficient to achieve the intended use and diagnostic requirement (none of the EPS320 protocols in Par 10.5 use more than 4)
Note 14 Sync Output	No	The EPS320 uses external sync, to synchronize between the amplifier and the stimulator. The EMS-XL has amplifier and stimulator integrated within the same system and thus external sync is not necessary.
Note 15 Stimulator power	No	The EMS-XL has integrated amplifiers, stimulator and control software, thus the requirement for separate power supply is irrelevant. The stimulator safety issues are covered by the following precautions: • The system includes an Isolation transformer (see User manual page IX) • Warning in User manual page X requires a defibrillator and external pacer in the EP procedure room • The EMS-XL amplifier and stimulator unit provides fixed rate stimulation in case of a fault of the cable connection of the unit to the computer. (page 2-1 of the user manual)
Note 16		Mennen Medical finds that the EPS320 use of the automation for ATP – Anti-tachycardia protocol, Trigger on ectopic beat and Stop on tachycardia may create a safety burden and thus decided to use the physician decision for these function as provided also on the EPS320
Note 17		**Warning** in EMS-XL User Manual page X requires a backup stimulator to be available in the EP procedure room
Note 18		The EMS-XL does not claim to contain an integrated Statistic and Inventory software package as does the GE-Prucka system. Such

		administrative package has no direct use on the EP procedure.
Note 19		The EMS-XL does not claim to have mapping capabilities. During EP procedures external devices can be used for mapping.
Note 20		The Prucka provides Vital singes audible indicator. The EMS-XL provides integrated tachycardia message. For other vital signs the User manual recommends to have an external patient monitor.

Clinical experience

The EMS-XL system has CE mark since December 2003 and is used by clinics out of the USA

Conclusion:

On the basis of the specification comparison we reach the conclusion that the EMS-XL is as safe, as effective, and performs as well as the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2007

Mennen Medical Ltd.
c/o Mr. Micha Oestereich
QA & RA Manager
4 Ha-Yarden St. POB 102 Rehovot
Yavne 76100
ISRAEL

Re: K071348
Trade Name: EMS-XL Cardiac Electrophysiology System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: August 29, 2007
Received: September 5, 2007

Dear Mr. Oestereich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K071348**

Device Name: EMS-XL Cardiac Electrophysiology System

Indications For Use:

EMS-XL is indicated to acquire, filter, digitize, amplify, display and record electrical signals obtained during electrophysiological studies and related procedures conducted in an electrophysiological laboratory. Signal types acquired include ECG signals, direct cardiac signals and pressure recordings. Physiological parameters such as the diastolic, systolic and mean blood pressure, heart rate and cycle length are derived from the signal data, displayed and recorded.
The system allows the user to monitor, display and record the signal data.

The system allows the user to monitor the acquisition data, review the data, store the data, perform elementary caliper-type measurements of the data, and generate reports on the data. The system may display and record data received from other medical devices typically used during these procedures, such as Ablation RF generators. The system incorporates a stimulator intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the human heart.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071348